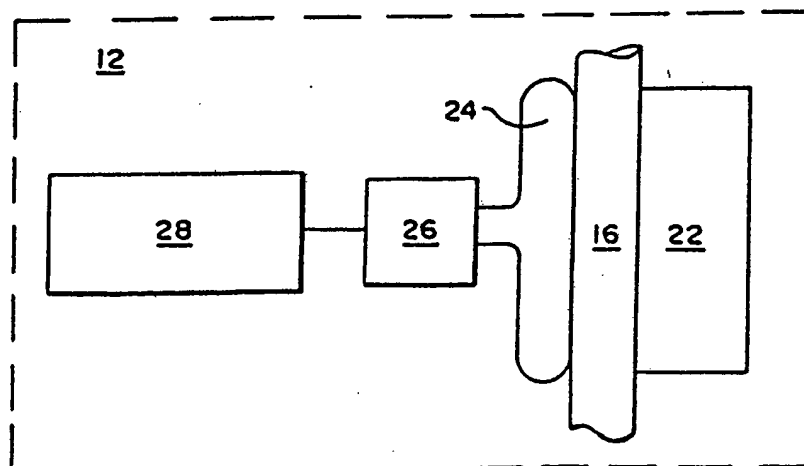




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61M 5/00	A1	(11) International Publication Number: WO 84/ 04685 (43) International Publication Date: 6 December 1984 (06.12.84)
(21) International Application Number: PCT/US84/00593 (22) International Filing Date: 16 April 1984 (16.04.84) (31) Priority Application Number: 497,369 (32) Priority Date: 23 May 1983 (23.05.83) (33) Priority Country: US (71) Applicant: BAXTER TRAVENOL LABORATORIES, INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). (72) Inventor: PEKKARINEN, Michael, O. ; 33 Cedar Lane, Lincolnshire, IL 60015 (US). (74) Agents: BENZIGER, Robert, A. et al.; One Baxter Parkway, Deerfield, IL 60015 (US). (81) Designated States: AU, BE (European patent), DE (European patent), FR (European patent), GB (European patent), JP, SE (European patent).		Published <i>With international search report.</i>

(54) Title: DIFFERENTIAL OCCLUSION SENSING METHOD AND APPARATUS



(57) Abstract

Method and apparatus to sense the downline pressure variations in the infusion tubing of a fluid infusion system on a differential basis. The sensor (12) includes a fixed block (22), against which the tubing (16) is pressed by a location indicator (24). The indicator (24) can be pneumatic, hydraulic or electronic, but functions to transmit the location or swelling of the tubing (16) to a transducer (26). The transducer (26) transmits a signal indicating the sensed location to a controller (28), such as a microprocessor. The controller (28) converts the location of the indicator (24) to a value indicative of the pressure in the tubing (16). In operation, the initial location of the tubing (16) is sensed a set time period after initiation of the infusion. If it is within a predetermined allowable range, the initial location is utilized as the base value. If the pressure changes by a preset differential amount from the base value, as determined by the sensor (12), the system will alarm.

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DIFFERENTIAL OCCLUSION SENSING
METHOD AND APPARATUS

BACKGROUND OF THE INVENTION

The present invention relates generally to fluid infusion systems and more particularly is directed to a method and apparatus for accurately detecting small changes in tubing dimensions to prevent high pressure infusion into the fluid infusion system.

The infusion of fluids into the human body is usually accomplished by means of an administration set in conjunction with metering apparatus which controls the rate of flow of fluid through the set. Peristaltic-type pumps, which function by repetitively compressing and expanding a section of tubing, have proven particularly attractive for use in metering apparatus since they do not introduce the possibility of leakage or contamination into the system, while providing positive control fo fluid flow through the system.

One form of peristaltic-type pump which is particularly well adapted for infusion applications is described in U.S. Patent No. 4,155,362. Basically, this pump construction includes individually spring-biased rollers in the pump rotor which provide a uniform compression force, and a spring-biased plunger which restricts the lumen of the administration set downline of the pump rotor



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to provide a back pressure against which the pump must work. This prevents the release of dissolved gas in the tubing section, assists in restoring the tubing to its original shape following compression by the pump, and prevents uncontrolled gravity flow in the event of pump failure.

A potential problem with this and other types of infusion systems relates to detecting pressure increases downline of the pump or pump restrictor in order to avoid patient harm which may occur as a consequence of excessive fluid pressure. Some prior systems have included sensing means with the pumping system, but these are ineffective downline of pumping systems which are isolated from downline pressure variations by some type of restrictor.

One prior attempt at solving this problem was the use of a push rod microswitch system. As the tubing would swell from the increase in pressure caused by an occlusion downline of the pump, the rod would activate the microswitch and cause an alarm and/or stop the pump. A basic problem with this type of microswitch system is that the calibration of the system requires that the switch respond at a specific position. Therefore, anything which affects the alignment and contact pressure between the push rod and the tubing has the capability of changing significantly the internal pressure which is required to cause the tubing to swell sufficiently in order to trigger the microswitch. Further, the stability of the mechanical system and the microswitch has to be accurate enough to measure as little as .001 inch



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travel. Variations such as spring fatigue and friction variations introduce other deviations in the operation. The cross sectional shape that the tubing has at the time of insertion into the pump
5 can vary from circular to extremely elliptical. This can result in differences as large as two to one in the dimension which is sensed by the push rod.

Further, the tubing itself will vary in wall
10 thickness and inside diameter by about .01 inch. In addition the tubing material itself will vary in the pressure it takes for it to swell a certain amount. The operating temperature range and age
15 of the tubing will cause variations in the amount of swelling per unit of pressure. These many variations can cause the actual pressure at which the push rod system will alarm to vary widely from infusion set to infusion set and with each insertion of the same tubing into the pump.



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SUMMARY OF THE INVENTION

In accordance with the present invention, a method and apparatus is provided to sense the downline pressure variations in the infusion tubing of a fluid infusion system on a differential basis. The invention allows for normal operation of the infusion system while monitoring any change in the tubing, swelling, and hence the internal pressure from the moment of pump initiation.

Thus, the initial location of the tubing is sensed a set time period after initiation of the infusion. The initial sensed location value is compared against a predetermined allowable range and is stored if it is within that range. The initial value thus takes all present factors into accord and is utilized as the base value. If the pressure changes by a preset differential amount from the base value amount as determined by sensing the change in the tubing location, the system will alarm.



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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram of an infusion system; and

Fig. 2 is a schematic diagram of a differential pressure sensor of the present invention.



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DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Fig. 1, there is shown diagrammatically an infusion system 10, which can incorporate the present invention of a differential pressure sensing system 12. A fluid to be infused or injected into a vein or artery is contained in a fluid source or reservoir 14. The fluid is coupled through a standard fluid set which includes a flexible, collapsible tubing 16, which can be in one or more segments as desired.

The tubing 16 couples the fluid through a drip chamber 18 and into a pump assembly 20. Although a peristaltic pump assembly 20 is preferred, and hereinafter described, the invention is not limited to any particular type of pumping system. After passing through the pump 20, the tubing is coupled through the pressure sensor 12 and then to the vein or artery (not shown) into which the fluid is to be infused. Although the sensor 12 is illustrated as a separate unit downstream of the pump 20, it preferably can be part of the pumping assembly rather than a separate unit. However, the sensor 12 operates independently of the particular pumping system, which is at least partially isolated, as by a restrictor, from the downstream pressure changes to be monitored.

Referring to Fig. 2, the pressure sensor 12 is best illustrated. The sensor 12 includes a fixed block 22, against which the tubing 16 is pressed by a location indicator 24. The indicator 24 can be pneumatic, hydraulic or electronic, but functions to transmit the location or swelling of



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the tubing 16 to a transducer 26. The transducer 26 transmits a signal indicating the sensed location to a controller 28, such as a microprocessor. The controller 28 converts the location of the indicator 24 to a value indicative of the pressure in the tubing 16. The transmitter 24 and transducer 26 can be separate units as shown, or can be one integral unit.

In operation, the pump 20 is activated causing an initial operating pressure to be developed, which may cause the tubing 16 to swell. The tubing position due to the tubing configuration or caused by the swelling is sensed by the indicator 24 and transducer 26 which transmits a signal to the controller 28. The controller 28 converts the position sensed to a pressure and compares the initial pressure value to an allowable pressure range, such as up to 20 psi. If the initial pressure value is within the allowable range, the value is stored and if it is outside the range, the controller 28 will cause the system 10 to alarm.

The controller 28 then utilizes the base location as the standard location to monitor the infusion process. If the location and hence the pressure varies at any time beyond a predetermined differential amount from the base pressure, such as 5 psi, then the system will alarm. The alarm limit can include a predetermined change in pressure from the base pressure and can include a maximum operating pressure for the system, such as 25 psi.



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Thus, an initial base location and hence pressure is obtained which eliminates variations in the tubing position, thickness, diameter and shape. In a hydraulic system the transmitter 24 will be formed from a flexible material such as silicone and will contain an incompressible fluid to transmit the location in the form of pressure to the transducer 26.

Modifications and variations of the present invention are possible in light of the above teachings. The controller 28 preferably converts the sensed location to pressure which then can be displayed for operator use; however, the controller also can operate directly on location changes without conversion. It is therefore to be understood that within the scope of the appended claims the invention may be practiced, otherwise than as specifically described.

What is claimed and desired to be secured by Letters Patent of the United States is:



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THAT WHICH IS CLAIMED IS:

1. A method of sensing and monitoring down-line fluid pressure in a fluid infusion system, comprising:

providing a fluid tubing;

5 providing a positive fluid flow in said tubing;

sensing an initial base location of said tubing;

monitoring the tubing location;

10 comparing the monitored location against the initial base operating location; and

setting an alarm if said monitored location exceeds a predetermined location differential.

2. The method as defined in claim 1 including:

sensing said initial base location after a predetermined time delay.

3. The method as defined in claim 1 including:

providing an absolute alarm location;

5 comparing the monitored location against the absolute alarm location; and

setting an alarm if said monitored location exceeds said absolute alarm location.

4. The method as defined in claim 1 including:

providing an allowable initial location range;

5 comparing said initial infusion operating base location against said allowable location range; and



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setting an alarm if said initial location is outside of said allowable location range.

5. The method as defined in claim 1 including:

converting said initial base location and said monitored location to a value indicative of the internal tubing pressure; and

setting said alarm if said monitored pressure exceeds a predetermined pressure differential.

6. The method as defined in claim 5 including:

sensing said initial infusion pressure after a predetermined time delay;

providing an allowable initial pressure range;

comparing said initial infusion operating pressure against said allowable pressure range; and

setting an alarm if said initial pressure is outside of said allowable pressure range.

7. The method as defined in claim 6 including:

providing an absolute alarm pressure;

comparing the monitored pressure against the absolute alarm pressure; and

setting an alarm if said monitored pressure exceeds said absolute alarm pressure.

8. An apparatus for sensing and monitoring downline fluid pressure in the fluid tubing of a fluid infusion system, comprising:

means adapted to be coupled to the fluid tubing for sensing the location thereof;



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means coupled to said sensing means for monitoring said sensed location and comparing it to an initial sensed location; and

10 means for setting an alarm if said sensed location exceeds a predetermined location differential.

9. The apparatus as defined in claim 8 including:

delay means for sensing said initial infusion location after a predetermined time delay.

10. The apparatus as defined in claim 8 including:

means for comparing the monitored location against an absolute alarm location; and

5 means for setting an alarm if said monitored location exceeds said absolute alarm location.

11. The apparatus as defined in claim 8 including:

means for comparing said initial infusion operating location against a predetermined allowable initial location range; and

5 means for setting an alarm if said initial location is outside of said allowable location range.

12. The apparatus as defined in claim 8 wherein:

said location sensing means include a fluid transducer adapted to be fluidly coupled to the
5 tubing.

13. The apparatus as defined in claim 8 including:



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means for converting said sensed location to
a value indicative of the internal tubing

5 pressure; and

means for setting said alarm if said monitored pressure exceeds a predetermined pressure differential.

14. The apparatus as defined in claim 13 including:

delay means for sensing said initial infusion pressure after a predetermined time delay;

5 means for comparing said initial infusion operating pressure against an allowable initial pressure range; and

means for setting an alarm if said initial pressure is outside of said allowable pressure
10 range.

15. The apparatus as defined in claim 14 including:

means for comparing the monitored pressure against an absolute alarm pressure; and

5 means for setting an alarm if said monitored pressure exceeds said absolute alarm pressure.



FIG. 1

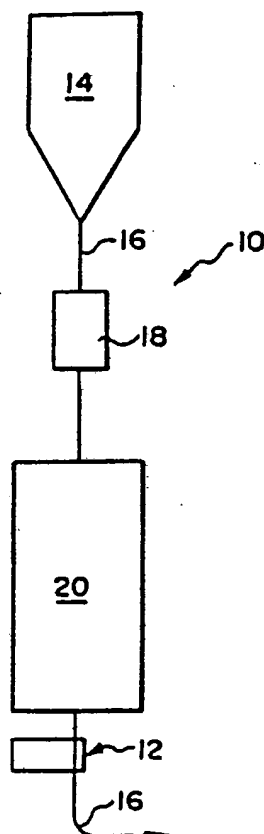
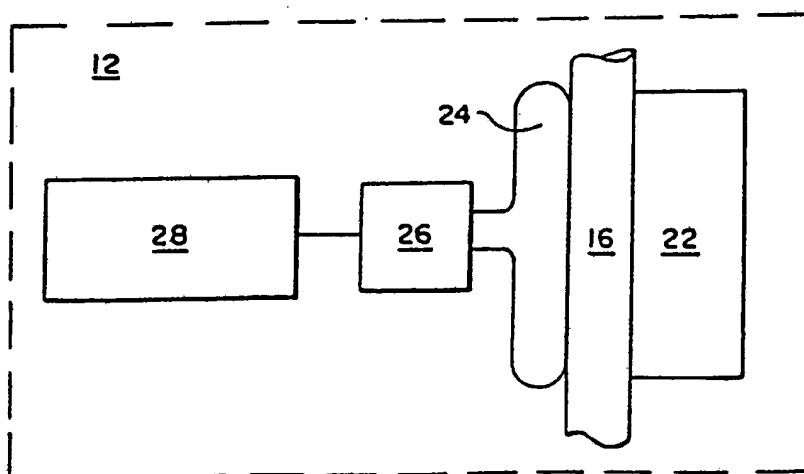


FIG. 2



INTERNATIONAL SEARCH REPORT

International Application No **PCT/US84/00593**

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹ According to International Patent Classification (IPC) or to both National Classification and IPC US: 604/49; 128/Digest 13 IPC: A61M 5/00																				
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched ⁴</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; border: 1px solid black;">Classification System</th> <th style="border: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="border: 1px solid black; text-align: center; vertical-align: top;">US</td> <td style="border: 1px solid black;">604/31, 53, 65, 67, 245, 246; 128/ Digest 13; 340/611, 614, 626</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁶</div>			Classification System	Classification Symbols	US	604/31, 53, 65, 67, 245, 246; 128/ Digest 13; 340/611, 614, 626														
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; border: 1px solid black;">Category ⁵</th> <th style="width: 60%; border: 1px solid black;">Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷</th> <th style="width: 30%; border: 1px solid black;">Relevant to Claim No. ¹⁸</th> </tr> </thead> <tbody> <tr> <td style="border: 1px solid black; text-align: center;">X, Y</td> <td style="border: 1px solid black;">US, A, 4,277,227, (JENKINS et al.) 7 July 1981 (67.07.81)</td> <td style="border: 1px solid black; text-align: center;">(1-15)</td> </tr> <tr> <td style="border: 1px solid black; text-align: center;">X, Y</td> <td style="border: 1px solid black;">US, A, 4,373,525 (KOBAYASHI) 15 February 1983 (15.02.83)</td> <td style="border: 1px solid black; text-align: center;">(1-3, 8-10, 12, 13)</td> </tr> <tr> <td style="border: 1px solid black; text-align: center;">A, P</td> <td style="border: 1px solid black;">US, A, 4,385,630 (GILCHER et al) 31 May 1983 (31.05.83) See column 5, lines 21-33 and column 6, lines 7-28</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td style="border: 1px solid black; text-align: center;">X, Y, P</td> <td style="border: 1px solid black;">US, A, 4,394,862 (SHIM) 26 July 1983 (26.07.83)</td> <td style="border: 1px solid black; text-align: center;">(1-15)</td> </tr> <tr> <td style="border: 1px solid black; text-align: center;">A, P</td> <td style="border: 1px solid black;">US, A, 4,431,425 (THOMPSON et al) 14 February 1984 (14.02.84)</td> <td style="border: 1px solid black;"></td> </tr> </tbody> </table>			Category ⁵	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸	X, Y	US, A, 4,277,227, (JENKINS et al.) 7 July 1981 (67.07.81)	(1-15)	X, Y	US, A, 4,373,525 (KOBAYASHI) 15 February 1983 (15.02.83)	(1-3, 8-10, 12, 13)	A, P	US, A, 4,385,630 (GILCHER et al) 31 May 1983 (31.05.83) See column 5, lines 21-33 and column 6, lines 7-28		X, Y, P	US, A, 4,394,862 (SHIM) 26 July 1983 (26.07.83)	(1-15)	A, P	US, A, 4,431,425 (THOMPSON et al) 14 February 1984 (14.02.84)	
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"d" document member of the same patent family</p> </div> </div>																				
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border: 1px solid black; padding: 5px;"> Date of the Actual Completion of the International Search ³ 28 June 1984 </td> <td style="width: 50%; border: 1px solid black; padding: 5px;"> Date of Mailing of this International Search Report ² 06 JUL 1984 </td> </tr> <tr> <td style="border: 1px solid black; padding: 5px;"> International Searching Authority ¹ ISA/US </td> <td style="border: 1px solid black; padding: 5px;"> Signature of Authorized Officer ⁷ J. J. BAUM </td> </tr> </table>			Date of the Actual Completion of the International Search ³ 28 June 1984	Date of Mailing of this International Search Report ² 06 JUL 1984	International Searching Authority ¹ ISA/US	Signature of Authorized Officer ⁷ J. J. BAUM														
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FURTHER INFORMATION. CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ¹¹

This International Searching Authority found multiple inventions in this international application as follows:

I. The method of sensing and monitoring of Claims 1-7.

II. The apparatus for sensing and monitoring of Claims 8-15.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.